MAR 16 2005

TORNIER

Implants Chirurgicaux

K050316

Summary of Safety and Effectiveness information
Special 510(k) – AEQUALIS Reversed Shoulder Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	***AEQUALIS Reversed Shoulder Prosthesis***
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier S.A.
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier S.A.
Mrs Mireille Lémery
Regulatory affairs & Quality Engineer
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38330 Montbonnot - France
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873
Aequalis Shoulder System, TORNIER SA, K952928
Bipolar Shoulder Prosthesis, BIOMET Inc, K991585
Delta Shoulder, DePuy Inc, K021478

6) Device description

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.

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SIRET : 070 501 275 000 13
R.C.S. : B 070 501 275
CODE APE : 331 B

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Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.
The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in the following changes:
1st change: addition of components in order to have the possibility to use multidirectional screws with the glenoid baseplate
2 types of components are added to the components of the *Aequalis Reversed Shoulder prosthesis*:
- Multidirectional screws in various length,
- Specific glenoid baseplate for multidirectional screws.

2nd change: addition of "fish-scales" on the peg of the humeral insert
3rd change: modification of packaging of polyethylene components

The indications for use already covered by the previous 510(k) clearance are not modified.

7) Materials
Metaphyseal inserts are made of ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2. The base of the glenoid implant is manufactured from Titanium alloy according to ISO standard 5832-3 and the anchoring screws are manufactured from Titanium alloy according to ISO standard 5832-3.

8) Indications
The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Mrs. Mireille Lémery
Regulatory Affairs and Quality Engineer
Tornier S.A.
161 rue Lavoisier
38330 Montbonnot
France

Re: K050316
Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 888.3660
Regulation Name: shoulder joint metal / polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: February 4, 2005
Received: February 14, 2005

Dear Mrs. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1/1 K050316

Indications for Use

510(k) Number (if known):

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

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Prescription Use × (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050316